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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, SANOFI-AVENTIS DEUTSCHLAND GMBH, and SANOFI WINTHROP INDUSTRIE, Plaintiffs, v. MYLAN GMBH, BIOCON LTD., BIOCON RESEARCH LTD., BIOCON SDN, BHD., and BIOCON S.A., Defendants.	C.A. No. 17-cv-09105-SRC-CLW

DEFENDANTS' POST-TRIAL BRIEF

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TABLE OF ABBREVIATIONS

Abbreviation	Full Name or Term	Trial Exhibit Number
’844 patent	U.S. Patent No. 9,526,844	JTX-3
Asserted Claims	Claims 21, 22, 25, and 30 of the ’844 patent	–
BD	Becton Dickinson	–
Chanoch	U.S. Patent No. 5,674,204	DTX-2280
Defendants	Mylan GmbH, Biocon Ltd., Biocon Research Ltd., Biocon Sdn, Bhd., and Biocon S.A.	–
DCA	DCA Design International – UK design firm that developed the SoloSTAR pen for Sanofi	–
GB priority application	GB Patent Application No. 0304822.0	DTX-2850
Giambattista	U.S. Patent No. 6,248,095	DTX-2283
Klitgaard	U.S. Patent No. 6,582,404	DTX-2284
NDA	New Drug Application	–
POSA	Person of Ordinary Skill in the Art	–
PTAB	Patent Trial and Appeal Board	–
Steenfeldt-Jensen	U.S. Patent No. 6,235,004	DTX-2282

I. INTRODUCTION

Upon approval of its NDA, Mylan GmbH intends to introduce its lower-cost insulin glargine pen product (the "Proposed Pen") as an alternative to Sanofi's high-priced Lantus SoloSTAR. Desperate to preserve its margins at the expense of American diabetic patients, Sanofi sued Mylan GmbH for alleged infringement of two formulation and sixteen device patents. *See* FOF ¶ 180. After the PTAB invalidated all claims of both formulation patents, and after Defendants whittled down fifteen of the sixteen device patents, four claims of the '844 patent are Sanofi's last hope in this litigation of preventing access to Mylan GmbH's lower-cost product.

Mylan GmbH's Proposed Pen, however, is radically different from the device described in the specification of the '844 patent originally filed seventeen years ago—the device Sanofi asked DCA to design in 2001. FOF ¶¶ 4-6, 177. In fact, the pens' operations are opposite. When the clutch described in the '844 patent is engaged, the clutch in the Proposed Pen is not. FOF ¶ 5. The piston rod in the '844 patent is solid, whereas the accused "plunger rod" in the Proposed Pen is hollow. FOF ¶¶ 181, 185. During dose administration, the '844 patent's pen requires the drive sleeve not rotate, while in the Proposed Pen the analogous lead screw must rotate. FOF ¶¶ 5-6.

These fundamental differences did not stop Sanofi from trying to improperly stretch its patent portfolio to cover a pen it did not invent. After reviewing a 2014 patent application publication by BD describing the design of the Proposed Pen, learning from that publication that BD's pen had an internally threaded piston rod, and discovering in late 2015 that Biocon would use the BD pen for a generic insulin glargine product, Sanofi filed an urgent "Track One" patent application with brand-new claims in an attempt to cover BD's unique design. FOF ¶¶180-182. Despite 13 years of previous patent prosecution relating to SoloSTAR, the application that led to

the '844 patent (filed after reviewing BD's design) was the first time Sanofi mentioned—let alone tried to claim—an internally threaded piston rod or piston rod holder. *See id*. But the '844 patent specification does not support these new claims. Indeed, there is a striking mismatch between the claims and the priority application originally filed in 2003. COL ¶56.

A. Sanofi Failed To Establish Infringement Despite Overbroad Claims

Despite Sanofi's dogged attempt to obtain claims that might encompass the Proposed Pen, Sanofi failed to establish infringement of any Asserted Claims at trial. As Mr. Quinn explained, the accused "sleeve" (setback) and "dose indicator" (dose set knob) are not "releasably connected," as claim 21 requires. FOF ¶¶ 8-13; *see also* FOF ¶¶ 3-6. The specification of the '844 patent only describes an embodiment in which the sleeve and dose indicator are connected in their nominal, resting state. That configuration is reflected accurately in claim 21 by the tense of the word "connected," which Sanofi chose to use. FOF ¶¶ 8-11, 13-14. When the phrase "releasably connected" is considered by the POSA in view of the intrinsic evidence, there is no infringement of any of the Asserted Claims, as Sanofi's expert, Dr. Reinholtz, admitted. FOF ¶ 15.

Further, although Dr. Reinholtz equivocated on whether the "piston rod holder" is the tower core alone, or the tower core together with the brake tower, neither alternative is "configured to … prevent the piston rod from rotating during dose setting" as claim 21 requires. FOF ¶¶ 16-20. Mr. Quinn explained how the setback—which Sanofi alleged to be the "sleeve" and "clutch" in claims 21 and 25—is the sole component configured to absorb torque during dose setting to prevent rotation, not the "piston rod holder." FOF ¶¶ 18-21, 31. And Dr. Reinholtz's surgically-altered modification of the Proposed Pen is irrelevant to the infringement analysis. The POSA interpreting the scope of claim 21 would not analyze a modified pen with missing components while vibrating it and holding it upside down. But that is how Dr. Reinholtz

conducted his "experiment," making his opinions based on the experiment inapposite. FOF ¶¶ 22-30. Because all Asserted Claims require this limitation, Mylan GmbH's Proposed Pen does not infringe any Asserted Claim on this second, independent basis.

Sanofi also failed to identify any clutch that is "further" (i.e., additionally) required by claim 25's dependence from claims 23 and 21, and Sanofi's own experts admitted an externally threaded component like a pipe nipple is not a "nut," which claim 30 requires. FOF ¶¶ 38-50.

B. Sanofi's Overbroad Claims Violate § 112

Sanofi's attempt to stretch claims based on the '844 patent's specification to reach Mylan GmbH's Proposed Pen causes the claims to violate § 112. To claim priority to the original application, the claims of the '844 patent must be fully supported by the specification originally filed in 2003. COL ¶¶ 14-18. However, because of the fundamental differences between the pen described in the '844 patent and the Proposed Pen, spanning between the lone embodiment in the '844 patent and BD's unique design proved to be a bridge too far. The '844 patent tries to claim an internally threaded piston rod, but there is no disclosure in the specification of a piston rod with internal threads. *See* FOF ¶¶ 183-86. Indeed, there is only one embodiment, and it describes a solid piston rod with external threads only. FOF ¶¶ 183, 185. Likewise, claim 21 uses generic functional language to claim a piston rod "holder" that is configured to prevent the piston rod from rotating during dose setting—i.e., a generic structure that "holds" configured to achieve a functional result. *See* FOF ¶¶ 205-06. The '844 patent fails to enable the full scope of the claim, however, because it does not teach all of the possible ways to configure a piston rod holder to prevent rotation. FOF ¶¶ 207-08.

C. Sanofi's Overbroad Claims Encompass Prior Art

In addition to causing § 112 problems, Sanofi's attempt to expand its patent claims exposed those claims to additional prior art. Sanofi stipulated, for example, that Giambattista, a

patent filed five years before the priority date of the '844 patent, discloses all but one limitation of claim 21. For that one ostensibly remaining limitation, Dr. Slocum claimed the limitation is not met only rarely—when the user is replacing an empty cartridge—and conceded that it is met when the pen is fully assembled. *See* FOF ¶¶ 133-34, 136. Sanofi also stipulated that Steenfeldt-Jensen, the prior art FlexPen product, and Chanoch meet nearly every limitation of the Asserted Claims. FOF ¶¶ 60-61, 128-29. And even where Sanofi contended Steenfeldt-Jensen, for example, lacks certain limitations, Dr. Slocum convincingly filled in those blanks, admitting Steenfeldt-Jensen's claim 6 discloses the threaded driving member limitations and the patent's specification describes an alternative configuration sufficient to meet the limitations of claim 21. FOF ¶¶ 73-74.

For all these reasons, Sanofi failed to meet its burden of proving infringement by a preponderance of the evidence and, in fact, the evidence establishes non-infringement. Defendants' evidence, on the other hand, clearly and convincingly proves the Asserted Claims are invalid as obvious and in violation of § 112. Defendants are therefore entitled to judgment in their favor, paving the way for Mylan GmbH to finally provide U.S. diabetic patients a lower-cost generic insulin glargine pen.

II. LEGAL STANDARDS

To avoid redundancy, Defendants respectfully direct the Court to Defendants' Proposed Findings of Fact and Conclusions of Law, wherein Defendants set forth the controlling authority on the legal issues relevant to this case. *See* COL ¶¶ 1-64.

III. THE PROPOSED PEN DOES NOT INFRINGE THE '844 PATENT

In the crowded field of injector pens—both now and at the time of the alleged invention in 2003—the common purpose and design constraints inherent in pen injectors caused certain basic components such as housings, cartridge holders, dial sleeves, and plunger rods to be

routinely used. FOF ¶ 3. Thus, while designing a unique pen can be difficult, that is exactly what BD achieved. FOF ¶¶ 2-4. BD respected the intellectual property existing at the time and, as Mr. Quinn explained, BD designed a unique pen that intentionally avoided patents held by Sanofi and others. FOF ¶¶ 3-4.

Indeed, the pen described in the '844 patent and the Proposed Pen operate in opposite ways. FOF ¶ 5. As a direct result of the fundamental structural and operational differences between the Proposed Pen identified in Mylan GmbH's NDA and the pen claimed in the '844 patent, Sanofi failed to meet its burden of establishing infringement of any of the Asserted Claims. FOF ¶¶ 1, 6; COL ¶¶ 1-2, 9-12.

A. Claim 21: The Sleeve Is Not "Releasably Connected" To The Dose Indicator

Claim 21 requires "a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator." FOF ¶ 7. Sanofi's infringement theory fails because the setback in the Proposed Pen (accused as the claimed "sleeve") is not "releasably connected" to the dose set knob ("DSK") (accused as the dose indicator), as claim 21 requires. FOF ¶ 7.

Claim 21 expressly requires the setback and DSK to be "connected." The claim language itself does not allow for the components to be merely connectable or capable of being connected. FOF ¶¶ 8-10, 13. Consistent with the claim language, the '844 patent—which describes only a single embodiment—describes how the clutch 60 and dose dial sleeve 70 are releasably ***connected*** during dose dialing and released during dose administration. FOF ¶¶ 8-9. Like a spring-loaded carabiner, the lone disclosed embodiment of the '844 patent involves inherent internal forces connecting the components when at rest. Application of an external force—initiated by a user pushing the button—is required to release the components from one another during the few moments of dose administration—thus, making them "releasably connected."

FOF ¶¶ 8-10, 13. The POSA would therefore understand "releasably connected" to mean that the sleeve and dose indicator are joined or "connected" to one another in their normal state but can be separated or "released" from that connected state only when acted upon by an outside force. FOF ¶ 10.

The Proposed Pen functions oppositely. The setback is ***disconnected*** when the pen is at rest and coupled only temporarily during dose administration. FOF ¶ 11. As Mr. Quinn explained, the '844 patent discloses structures akin to a spring to ensure the clutch and dose dial sleeve are connected at rest. FOF ¶ 12; *see also* FOF ¶ 10. The Proposed Pen lacks any corresponding feature. FOF ¶ 12. The POSA would understand the Proposed Pen's configuration as "connectable," but not "releasably connected." FOF ¶ 13. As a result, the Proposed Pen does not infringe claim 21. FOF ¶ 13; COL ¶¶ 2-3, 10.

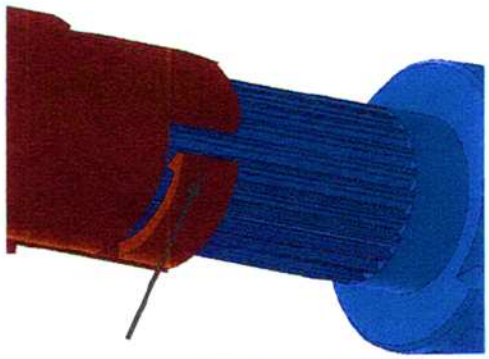
Sanofi's argument that "releasably connected" means components can "be connected or disconnected" at any point during the pen's operation completely disregards the context provided by the specification and the claim language. FOF ¶ 14; COL ¶¶ 2-3. Under the correct view of the claim language as described by Mr. Quinn, in which the sleeve and dose indicator are "connected" in their nominal, resting state, even Sanofi's expert admits there is no infringement of any Asserted Claim. FOF ¶ 15.

B. Claim 21: The Accused "Piston Rod Holder" Is Not Configured To Prevent The Piston Rod From Rotating During Dose Setting

Claim 21 further requires a "piston rod holder" that is "configured to (i) prevent the piston rod from rotating ***during dose setting***." FOF ¶ 16. Dr. Reinholtz initially said the tower core alone was the claimed piston rod holder. But on cross-examination, he changed his theory

to accuse the tower core in combination with the brake tower to satisfy this limitation.[1] FOF ¶ 17. However, neither the tower core alone nor the tower core combined with the brake tower satisfies claim 21 because they are not configured to prevent rotation during dose setting.

As Mr. Quinn explained, the components of the Proposed Pen that allegedly "hold" the plunger rod are not configured to prevent the plunger rod from rotating during dose setting, because a ratchet on a different component, the setback (shown here), absorbs any frictional torque that might otherwise reach the plunger rod when a user is setting a dose. FOF ¶¶ 19-20. Unlike the claimed device, the Proposed Pen uses the setback—the accused "sleeve" and "clutch"—to prevent rotation during dose setting, ***not*** a "piston rod holder." FOF ¶ 20. As a result, the Proposed Pen cannot and does not infringe claim 21. FOF ¶ 21; COL ¶ 10.


Ratchet on Setback

Dr. Reinholtz nevertheless attempted to support Sanofi's infringement claims with a flawed experiment using a heavily modified version of the Proposed Pen. Specifically, Dr. Reinholtz used a knife to cut off most of the tower core and removed pieces of the Proposed Pen to test his theories. FOF ¶ 22. Doing so, however, resulted in a pen that could no longer be considered the Proposed Pen and that Dr. Reinholtz knew would no longer operate correctly. FOF ¶ 22.

Moreover, the unintended consequences of Dr. Reinholtz's modifications negate any probative value of the purported results. FOF ¶¶ 23-28. First, removal of the C-shaped, sleeve-

[1] Notably, Dr. Reinholtz interprets two components as satisfying a single limitation when it suits him, such as here, and also interprets one component as satisfying two limitations elsewhere, such as regarding the "sleeve" in claim 21 and "clutch" in claim 25. FOF ¶ 18.

like portion of the tower core virtually eliminated the tower core's support of the lead screw and provided additional space in which the lead screw could move. FOF ¶¶ 23-24. Second, removing the dose stop component also created additional space and allowed the setback, and therefore the lead screw, to move more freely. FOF ¶¶ 23-24. Third, Dr. Reinholtz's conscious decision to advance the stopper away from the plunger rod further changed how the plunger rod could move within the pen. FOF ¶¶ 23-24. In particular, the plunger rod cannot rotate if it is already against the rubber stopper, but Dr. Reinholtz's modification eliminated that additional constraint on the plunger rod. FOF ¶¶ 23-24. Because Dr. Reinholtz's modifications changed the Proposed Pen and its components' interoperations so materially, his experiment failed to demonstrate that claim 21 is met by the Proposed Pen.

At most, Dr. Reinholtz demonstrated certain modified pieces of the Proposed Pen could be re-assembled to allow the plunger rod to rotate when oriented needle-side-up and assisted by shaking and gravity. Claim 21, however, is not directed to preventing rotation under those circumstances. FOF ¶¶ 25-28. As a result, the experiment is not even germane to whether an unmodified Proposed Pen contains "a piston rod holder" "configured to prevent the piston rod from rotating during dose setting." FOF ¶¶ 25-29; COL ¶ 11. As Mr. Quinn testified, and neither Sanofi nor its witnesses rebutted, the POSA would not use an experiment like Dr. Reinholtz's to evaluate a pen injector or determine how its components function. FOF ¶ 30.

Aside from Dr. Reinholtz's experiment, the only documentary evidence Sanofi offered refers only to dose administration, not dose setting as specifically required by the claim, and is therefore irrelevant to claim 21. FOF ¶ 31; COL ¶ 10. Accordingly, the Proposed Pen does not meet the limitations of claim 21 of the '844 patent. FOF ¶ 32; COL ¶¶ 9-12.[2]

[2] Because claim 21 is not infringed, dependent claims 22, 25, and 30 are not infringed, either. COL ¶ 12; *see* FOF ¶ 33.

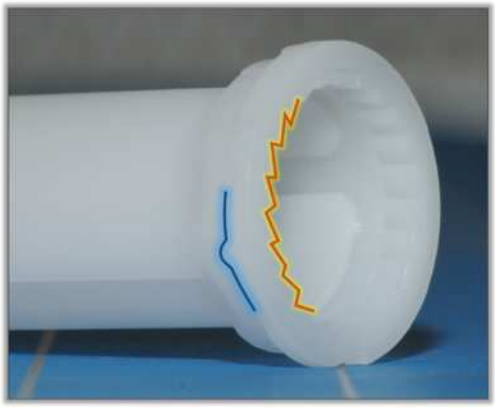
C. Claim 25: Sanofi Failed To Identify The Required "Further" Clutch

Claim 25 depends from claim 24, which in turn depends from claim 23, which depends from Claim 21. Neither claim 23 nor asserted claim 25 is infringed.

First, Sanofi failed to identify a separate component as the claimed "clutch" in claim 23 (and therefore also required by asserted claim 25). FOF ¶¶ 37, 40. Claim 21 requires a "sleeve" that is releasably connected to the dose indicator, and claim 23 requires the device of claim 21, "further comprising a clutch." Dr. Reinholtz identified the setback as the sleeve required by claim 21 but failed to identify any additional clutch component to satisfy claim 23. FOF ¶¶ 37-38. Instead, Dr. Reinholtz asserted the setback is both the sleeve and clutch, but that contention disregards the explicit claim language, which is improper.[3] FOF ¶¶ 38-39; COL ¶¶ 3, 5, 8.

Claim 23 expressly requires the device of claim 21, "***further*** comprising a clutch." FOF ¶ 38. By statute, a dependent claim must narrow the scope of the claim from which it depends, lest the dependent claim be invalid. COL ¶ 5. Thus, if claim 23 is not invalid, there must be a difference in the scope of claims 21 and 23. But Sanofi failed to identify a limitation in claim 23 that narrows claim 21 in any way. The only way to maintain validity of claim 23 is by respecting the inventors' deliberately chosen word—"further"—and finding claim 23 to require an additional component relative to claim 21. FOF ¶¶ 40-41; COL ¶¶ 3-5, 7-8. Indeed, Dr. Reinholtz agreed that if "further comprising" requires a separate component, there is no infringement. FOF ¶ 42. As a result, neither claim 23 nor asserted claim 25 is infringed. FOF ¶ 42; COL ¶¶ 10, 12.

[3] Dr. Reinholtz's contentions in this regard—where one component allegedly satisfies two claim limitations—stand in stark contrast to, and are inconsistent with, his position regarding the "piston rod holder," where he argued two components allegedly combine to satisfy one claim limitation (as described above with respect to claim 21). FOF ¶¶ 17-20, 40.



Second, claim 25 is not infringed. Claim 25 requires that "the clutch provides audible clicks[.]" FOF ¶ 43. Sanofi identified certain "setback teeth" (shown with a yellow annotation in the image reproduced here) as portions of the setback that click. DTX-2442; FOF ¶ 43. Although the identified setback teeth do click during dose correction, they have no role whatsoever in the clutching function, which is performed by entirely separate teeth highlighted in blue. FOF ¶ 43. Sanofi did not establish why teeth unrelated to, and therefore having no role in, the clutching function should be considered part of the claimed "clutch." FOF ¶ 43. Because the accused "clutch" does not provide audible clicks, the Proposed Pen does not infringe claim 25. FOF ¶ 43; COL ¶ 10-12.

D. Claim 30: The Accused "Dose Stop" Is Not A "Nut"

Claim 30 requires a "nut that tracks each set dose of medicament delivered." The POSA would understand a "nut" to have internal threads. FOF ¶¶ 44-48. Indeed, Dr. Reinholtz agrees with Mr. Quinn that the usual meaning of "nut" refers to an internally threaded component. FOF ¶ 49. The specification fails to expressly or implicitly define "nut" otherwise, and the lone embodiment in the '844 patent has an internally threaded nut, confirming the claimed "nut" is internally threaded. FOF ¶ 49.

The Proposed Pen does not have a "nut" that tracks doses of medicament. FOF ¶¶ 44-48. Ignoring the plain and ordinary meaning of "nut," Sanofi identified a component of the Proposed Pen called the "dose stop." But the dose stop has only external threads. Nonetheless, Sanofi argued through Dr. Reinholtz that the claim does not require internal threads and "some nuts have external threads." FOF ¶¶ 45-47. Dr. Reinholtz, however, failed to opine that such a component without internal threads would classify as a nut ***to the POSA***. FOF ¶¶ 45-49. In

fact, when shown a picture of a pipe nipple bearing only external threads, Dr. Reinholtz admitted that "[he] generally wouldn't describe that as a nut." FOF ¶ 47. Further, Dr. Slocum testified that removing internal threads from a "nut element" would mean that "in some respects, it's no longer a nut." FOF ¶ 48. Indeed, items with only external threads, like pipe nipples, are not typically referred to as nuts. FOF ¶ 49. The plain and ordinary meaning of "nut" does not include externally threaded components and as a result, the Proposed Pen does not infringe claim 30. FOF ¶ 50; COL ¶¶ 2, 6, 10.

IV. THE '844 PATENT IS INVALID

A. The '844 Patent Is Invalid Under Section 112

The '844 patent is invalid pursuant to 35 U.S.C. § 112 for lacking written description and failing to enable the full scope of the asserted claims. First, the '844 patent does not describe or enable embodiments having an internally threaded piston rod. Second, to the extent the lone embodiment in the patent has a "piston rod holder," that holder is not configured to prevent rotation during dose setting.[4]

The '844 patent's § 112 shortcomings are a direct result of Sanofi's attempt to improperly stretch a patent family originally intended only to cover its SoloSTAR pen to encompass the unique Proposed Pen developed independently by BD. FOF ¶ 178. Sanofi approached DCA in 2001 to design an injector pen, and the first patent applications were filed in Great Britain and the U.S. in March 2003 and 2004, respectively. FOF ¶¶ 177, 179. As Mr. Veasey, a named inventor of the '844 patent and DCA employee, explained, the first applications were intended to cover DCA's design "Concept 12." FOF ¶ 179. From 2004 to 2016, Sanofi filed over a dozen

[4] Notably, the alleged "piston rod holder" in the '844 patent, insert 16, could hold only an externally threaded piston rod. FOF ¶ 176. There is no disclosure in the '844 patent demonstrating possession of a structure that holds an internally threaded piston rod like the plunger rod in the accused Proposed Pen or teaching the POSA how to make and use a "holder" for an internally threaded piston rod. FOF ¶ 176.

other related applications, none of which describe or claim an internally threaded piston rod. FOF ¶ 180.

Only after publication of a patent application describing BD's new pen (disclosing a hollow plunger rod with internal threads), and after it became public knowledge that Biocon would use BD's new pen for an insulin glargine product, did Sanofi file yet another patent application with claims reciting—for the first time—an internally threaded piston rod. FOF ¶¶ 181-82. The Federal Circuit recently invalidated a patent under §112 in *Quake v. Lo*, 928 F.3d 1365 (Fed. Cir. 2019), under nearly identical factual circumstances:

> [T]he first time Quake tried to cover random MPS with this specification was ***after the publication of Lo's patent application*** directed to random MPS: Quake then canceled all his pending claims and replaced them with claims covering random MPS, ***creating a mismatch between the claims and the originally filed specification***. An invention is usually expressly described in the specification; there is no reasonable argument for that being the case here.

Id. at 1374 (emphasis added); *see also* COL ¶ 56. Sanofi similarly created a mismatch between the specification filed in 2003 and the claims filed in 2016. *See* FOF ¶¶ 179-80, 182. As a result of Sanofi's unsupported claims, the '844 patent is invalid pursuant to §112. FOF ¶¶ 175-76; COL ¶ 52-56.

1. There Is No Support For An Externally Threaded Driving Member Engaged With An Internally Threaded Piston Rod

Claim 21 recites "a piston rod comprising either an internal or an external fourth thread." FOF ¶ 183. Claim 21 also requires a "driving member comprising a third thread," where the third thread engages with the fourth thread of the piston rod. FOF ¶ 183. But, as Mr. Leinsing explained, the '844 patent does not describe either an internally threaded piston rod or an externally threaded driving member. FOF ¶ 183. The reason for the lack of disclosure is that Sanofi did not invent those features.

Instead, the sole embodiment disclosed in the '844 patent's specification has an

externally threaded piston rod that engages with the internal threads located on the drive sleeve. FOF ¶¶ 185-86. There is no explicit, or even implicit, suggestion in the specification that the piston rod could instead somehow be configured to have internal threads, or the drive sleeve reconfigured to have external threads engaged with the piston rod.[5] FOF ¶ 184. And, even if there were, there is certainly no explanation for how one might modify other components in the device to accommodate such changes. FOF ¶¶ 184-86; COL ¶¶ 57-58.

Sanofi nevertheless argued the scope of claim 21 includes "internally threaded piston rods," allegedly based on generic statements in the '844 patent. FOF ¶ 191. According to Dr. Slocum, the POSA could thread a piston rod only two ways, internal or external, meaning the POSA would understand the '844 patent's non-specific statements as implicitly disclosing an internally threaded piston rod as an option. FOF ¶ 191. But the cited portions of the '844 patent do not disclose an internally threaded piston rod anywhere. FOF ¶ 185. And there is no background prior art to support Sanofi's claims, either. FOF ¶¶ 186, 192.

Although the face of the '844 patent lists about 200 references, Sanofi's expert, Dr. Slocum, was unable to identify ***a single piece*** of injector pen prior art describing a piston rod with internal threads. FOF ¶ 186. Instead, Dr. Slocum cited two patents—located by Sanofi's counsel—that relate to motorized pumps. FOF ¶ 186. The Spinello patent describes a motorized device for injecting anesthetic. FOF ¶ 187. The second patent, Kamen, describes an infusion pump and refers to a "piston member," but not a piston rod. FOF ¶ 188. Dr. Slocum stated, in conclusory fashion, that these patents describe "drug delivery device[s]," but he failed to come forward with any evidence as to why the POSA would consider them pertinent prior art or how

[5] The only external threads on the drive sleeve 30 engage with internal threads on nut 40. FOF ¶ 184. There is no description of external threads on drive sleeve 30 that engage with a piston rod, and no description of the "stinger" sketched by Dr. Slocum. FOF ¶ 184.

the POSA could possibly implement any teachings from them into the embodiment of the '844 patent. FOF ¶ 189; COL ¶¶ 13, 17, 57. Neither reference is pertinent to the field of pen injectors. FOF ¶ 190; COL ¶¶ 27-28.

With nothing in the specification and no injector pen prior art to rely on to support his claim that the POSA would somehow "just know" how to implement an internally threaded piston rod, Dr. Slocum drew an impractical variation of the embodiment in the '844 patent with an externally threaded "stinger" added to the drive sleeve. FOF ¶ 191. There is no basis to credit Dr. Slocum's testimony on this point. FOF ¶ 192.

First, the fact that neither Sanofi's counsel nor Dr. Slocum could find a single injector pen with an internally threaded piston rod before the priority date undermines Sanofi's claim that the POSA would readily understand the '844 patent as implicitly disclosing one. *See* FOF ¶¶ 186, 192; COL ¶¶ 56-57. Second, as Mr. Leinsing explained, implementing an internally threaded piston rod to the embodiment in the '844 patent would cause manufacturing problems and increase costs. FOF ¶ 193. As a result, Dr. Slocum's suggested "stinger" is contrary to the specification's express goals for the pen to be "robust in construction" and "cheap to manufacture." FOF ¶ 193. And third, Dr. Slocum's testimony regarding the POSA's understanding in 2003 lacks credibility because he had no experience with injector pens at that time. FOF ¶ 194. Instead, Dr. Slocum had to backfill his lack of knowledge about pens in that time period via post-hoc conversations with Mr. Veasey, a named inventor and Sanofi witness. FOF ¶ 194.[6]

[6] Sanofi's pre-trial brief also appears to argue that claim 21 has written description support simply because the 2016 application that led to the '844 patent contained a claim directed to an internally threaded piston rod. ECF No. 506 at 34-35. Sanofi is incorrect. In the context of continuation patents claiming priority to an earlier application, the question is whether "the inventor had possession, as of the filing date ***of the application relied on***, of the specific subject matter later claimed by him." COL ¶ 16.

The foregoing reasons are clear and convincing evidence that the POSA in 2003 would have understood that the inventors did ***not*** possess an injector pen with an internally threaded piston rod or an externally threaded driving member engaged therewith. Accordingly, claim 21 is invalid for lack of written description. FOF ¶ 195; COL ¶¶ 14, 17-18, 53-58.

Defendants have also shown by clear and convincing evidence that claim 21 is invalid as not enabled. *See* COL ¶¶ 13-15, 52. The '844 patent provides no instructions for how to make and use an injector pen having an internally threaded piston rod engaged with an externally threaded driver. FOF ¶ 196. As named inventor Robert Perkins conceded, redesigning the externally threaded piston rod to have internal threading would require making additional changes to multiple other components to have "a theoretically functional design" because "it's part of a complex system." FOF ¶ 196; *see* COL ¶ 59. Mr. Leinsing also explained that redesigning the pen to have an internally threaded piston rod and externally threaded driving member would take considerable time and experimentation, result in a pen with a larger diameter, and be difficult to manufacture. FOF ¶ 197. As the Federal Circuit stated, simply "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); COL ¶ 59. Here, with no guidance—less than a germ—the POSA, which Dr. Slocum opined could be a recent college graduate with no injector pen experience, would not have been able to modify the embodiment in the '844 patent to make and use a pen with an internally threaded piston rod and externally threaded driving member. FOF ¶ 198. Thus, claim 21 is invalid for lack of enablement. FOF ¶ 198; COL ¶¶ 15-18, 59-61.

2. No Support For Claiming A Piston Rod Holder Configured To Prevent Rotation During Dose Setting

Claim 21 also requires a "a piston rod holder that is rotatably fixed relative to the housing

and configured to (i) prevent the piston rod from rotating during dose setting." FOF ¶ 199. The '844 patent, however, does not describe any component as a "piston rod holder," let alone one configured to prevent the piston rod from rotating. FOF ¶¶ 200-04. Nor does it teach how to make and use the full scope of the claim, which purports to cover every possible way of achieving the function of "holding" a piston rod and being configured to prevent rotation. FOF ¶¶ 205-08; COL ¶¶ 2, 15-16, 53, 59.

The '844 patent never uses the phrase "piston rod holder" except in the claims. FOF ¶ 200. Accordingly, there is no express description of a holder "configured to prevent" rotation during dose setting as claim 21 requires. FOF ¶ 200. Sanofi's expert, Dr. Slocum, contended that insert 16 corresponds to the claimed "holder" because it "holds" the piston rod and if insert 16 were not present, the piston rod could rotate during dose setting. FOF ¶ 201. But this ignores the specification, which describes the ***piston rod's*** design itself as key to preventing rotation, not insert 16's: "[r]otation of the piston rod 20 is prevented due to the opposing directions of the overhauled and driven ***threads on the piston rod*** 20." FOF ¶ 202 (emphasis added). In fact, insert 16 is configured to allow rotation of the piston rod through its threaded bore during dose administration, demonstrating that the piston rod's configuration, not that of the "holder," is what truly prevents rotation during the claimed dose setting phase. FOF ¶¶ 202-03. Thus, the disclosure of the '844 patent demonstrates to the POSA that the inventors were not in possession of the claimed "holder," rendering claim 21 invalid for lack of written description. FOF ¶¶ 203-04; COL ¶¶ 56-58.

Claim 21 is also invalid for lack of enablement, which requires the specification to enable the full scope of the claims. COL ¶¶ 59-61. Claim 21 is written with functional words, referring to a holder (i.e., a thing that performs the function of holding) and having a configuration that achieves a functional result: preventing rotation during dose setting. FOF ¶ 205. The Court's

Claim Construction Order declined to adopt a means-plus-function construction, which would have limited the term to structures described in the specification that perform the claimed functions, and equivalents thereto. FOF ¶ 206; COL ¶ 52. As a result, the scope of claim 21 purports to cover all ways of configuring a "holder" to prevent rotation of the piston rod, including opposing threads (as disclosed), flats (not disclosed), splines (not disclosed), and keys (not disclosed). FOF ¶ 206. Aside from opposing threads (on the piston rod, not insert, at that), the '844 patent does not teach the POSA how to configure a holder to prevent rotation. FOF ¶ 207. As a result, the POSA could not make and use the full scope of the claims without undue experimentation and claim 21 and all claims depending therefrom are also invalid for lack of enablement. FOF ¶ 208; COL ¶¶ 15-18, 52, 59-61.

B. The Prior Art Renders The '844 Patent Obvious

Defendants have met their burden of proving the '844 patent was obvious to the POSA in view of the prior art. Indeed, Sanofi stipulated that almost all limitations are met by the prior art, and the evidence at trial—including admissions by Sanofi's expert, Dr. Slocum—demonstrate the limitations purportedly missing were also in fact disclosed in the prior art.

The obviousness inquiry requires ascertaining (1) the level of ordinary skill in the field; (2) the scope and content of the prior art; (3) what difference, if any, existed between the claimed invention and the prior art; and (4) any alleged secondary evidence bearing on obviousness. COL ¶ 19; *see also* COL ¶¶ 20-28. Obviousness is determined from the perspective of the POSA as of the priority date, assumed here to be March 3, 2003. COL ¶ 22; FOF ¶¶ 52-54.

1. The POSA

Mr. Leinsing explained that the POSA is a person that by "educational [or] practical experience, [had] at least the equivalent of a bachelor's degree in mechanical engineering or related field. That person would also have approximately three years of practical experience

with medical device design and manufacturing, or at least the understanding of the basic medical design and manufacturing as it pertains to pen injectors, gears, pistons, and those types of components." FOF ¶ 55. He further explained that his opinions would be the same even if they were premised upon Dr. Slocum's definition of the POSA. FOF ¶ 56.

Notably, Mr. Leinsing was proffered and accepted as an expert in the field of pen injectors and had significant experience with pen injectors before the priority date.[7] FOF ¶ 57. Dr. Slocum, by contrast, had no experience with pen injectors until this case and was only offered as an expert in mechanical systems, not pen injectors. FOF ¶ 58. As a result, while Dr. Slocum may meet the definition of the POSA by having mechanical engineering education and experience with other types of medical devices, he had ***no professional knowledge*** of injector pens until he began working for Sanofi in this litigation. FOF ¶ 58.

2. Steenfeldt-Jensen In View Of Chanoch Render The Asserted Claims Obvious

As Sanofi stipulated, Steenfeldt-Jensen describes a pen injector that meets each of the limitations recited in claim 21, except "a driving member having a third thread" that engages with the external thread of a piston rod. FOF ¶ 60. But Steenfeldt-Jensen teaches alternative embodiments having a threaded driving member, and Dr. Slocum admitted that the driving member limitation is met by at least Steenfeldt-Jensen, claim 6. FOF ¶ 60. To the extent there was any doubt that threaded driving members were known in the prior art, Sanofi also stipulated that Chanoch discloses a threaded driving member, as required by claim 21 of the '844 patent. FOF ¶ 61.

[7] Mr. Quinn was also accepted as an expert in pen injectors. FOF ¶ 59. Dr. Reinholtz, like Dr. Slocum, was not proffered as an expert in the field. FOF ¶ 59.

(continued...)

a. Claim 21: Steenfeldt-Jensen And Chanoch Teach An Internally Threaded Driver Tube

i. Steenfeldt-Jensen Teaches A Threaded Driving Member

Prior art patent Steenfeldt-Jensen[8] describes five primary embodiments of injector pens with components that drive a piston rod to dispense medicine. FOF ¶¶ 63-65. In its fifth embodiment, Steenfeldt-Jensen describes an injector pen with a driver tube 85, piston rod 6, and member 40. FOF ¶ 65. The driver tube has a slot with rounded ends that engages with the piston rod so that they rotate together, but the driver may move axially relative to the piston rod. FOF ¶ 65. The piston rod is also engaged with threads in member 40, which is rotationally and axially fixed to the housing, so that when the piston rod rotates, it moves forward to dispense medication. FOF ¶ 65.

Although the fifth embodiment situates the slot (i.e., the "piston rod guide") within the driver tube 85 and the internally-threaded bore (i.e., the "nut member") within the member 40, Steenfeldt-Jensen expressly teaches an alternative option that exchanges the slot and threaded bore in the driver tube 85 and member 40, such that the driver tube alternatively comprises internal threads. FOF ¶ 66. Further, after description of its first embodiment, Steenfeldt-Jensen states that "[e]mbodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube and such embodiment will not be beyond the scope of the invention." FOF ¶ 67.

As Mr. Leinsing explained, the POSA would have understood Steenfeldt-Jensen as teaching two alternative approaches for the driver tube: (1) as in the illustrated embodiment, where the driver tube may include the rectangular bore such that the piston rod is rotated relative to the nut member; or (2) as in the disclosed alternative, where the driver tube may include the

[8] Sanofi stipulated that Steenfeldt-Jensen, issued in 2001, is prior art. FOF ¶ 62.

internally-threaded bore such that the nut member is rotated relative to the piston rod. FOF ¶¶ 68-72. Dr. Slocum, moreover, admitted that the POSA, upon reading Steenfeldt-Jensen, would exchange the threads and slot:

> Q. … "Embodiments may be imagined wherein the piston rod guide is provided in the wall 4 and a nut element is rotated by the driver tube, and such embodiment will not be beyond the scope of the invention." You see that; right?
> A. That's what the words say.
> Q. That's what the words say. And you don't disagree that implementing what that word says involves flipping the slot and the thread; correct?
> A. ***If you just read the words, you will flip them***.

FOF ¶ 73 (emphasis added). Dr. Slocum also admitted that claim 6 in Steenfeldt-Jensen expressly claims a threaded driver. FOF ¶ 74. As a result, it cannot reasonably be disputed that Steenfeldt-Jensen discloses the limitations of claim 21. FOF ¶ 75; COL ¶¶ 29-30, 32-36.

ii. Chanoch Teaches A Threaded Driving Member

Sanofi's assertion that using a threaded driver would be "stupid" or that the POSA would not do so—despite Steenfeldt-Jensen's express teachings and claims—are directly rebutted by Chanoch, a U.S. Patent directed to a "medication delivery pen" that issued in 1997.[9] FOF ¶¶ 76-77. Chanoch describes a threaded driving member engaged with a threaded piston rod, as Sanofi stipulated. FOF ¶ 78. Like driver tube 85 in Steenfeldt-Jensen, Chanoch describes a nut 110 that is fixed axially but free to rotate relative to the housing. FOF ¶ 79. Along its internal surface, the nut 110 includes threads that engage external threads 123 of a leadscrew 120. FOF ¶ 80. When the user pushes on the button during dose dispensing, nut 110 is rotated, thus driving the leadscrew 120 axially to dispense medication. FOF ¶ 81. To the extent the POSA had any reservations regarding whether the alternatives described in Steenfeldt-Jensen could be implemented, any doubts would have been resolved by Chanoch, which is prior art in the same injector pen field as Steenfeldt-Jensen and the '844 patent. FOF ¶ 82; COL ¶¶ 20, 23, 25-36.

[9] Sanofi stipulated that Chanoch is prior art. FOF ¶ 78.

iii. Dr. Slocum's Arguments Are Unavailing

Even though the prior art plainly disclosed threaded driving members, Sanofi relies entirely on Dr. Slocum to contend the POSA would not be motivated to "modify" Steenfeldt-Jensen because of purported concerns about injection force. FOF ¶ 83. Dr. Slocum's opinions are flawed for several reasons.

First, Dr. Slocum's reading of Steenfeldt-Jensen improperly treats the single patent as if it were a collection of independent references, rather than considering the teachings of the entire patent as a whole. COL ¶¶ 34-35. Dr. Slocum opined that Steenfeldt-Jensen does not teach a threaded driver, and even characterized Steenfeldt-Jensen's express teaching of the swap as likely a "lawyer add-on," notably without any support for the assertion. FOF ¶ 84. To support his claim, Dr. Slocum asserted Steenfeldt-Jensen's suggestion for an internally threaded driver tube is limited to only the first embodiment.[10] FOF ¶ 85. Dr. Slocum's opinion is incorrect because it ignores the other express teachings in the description of the invention section and the extensive similarities between the first and fifth embodiments that would have led the POSA to understand the applicability of concepts across the disclosed embodiments. FOF ¶¶ 84, 86; COL ¶¶ 29-30, 34-36. Indeed, Dr. Slocum admitted that the first and fifth embodiments operate the same way during dose dispensing. FOF ¶ 87. Therefore, there is no need to "modify" Steenfeldt-Jensen to arrive at a threaded driving member—Steenfeldt-Jensen expressly teaches one to the POSA. FOF ¶ 88.

Second, Dr. Slocum's opinion incorrectly assumes the POSA in 2003 would rely on injection force as the ultimate guiding principle when designing an injector pen. FOF ¶ 89. Dr.

[10] Sanofi attempted to bolster this argument by relying on Steenfeldt-Jensen's provisional application, which Dr. Slocum stated disclosed only the first and second embodiments. *See* FOF ¶ 85. But embodiments in the provisional application are irrelevant to what would be obvious to the POSA in view of the issued Steenfeldt-Jensen patent. COL ¶¶ 34-35.

Slocum's assumption is derived solely from what he was told by Mr. Veasey during the pendency of this case. FOF ¶ 89. In reality, DCA documents at the time of the alleged invention state that when designing the SoloSTAR pen, injection force was only given the weight of a "marketing / project desirable" characteristic, ranked a "3" on a scale from 1 to 5 and behind numerous other considerations ranked higher at 4 ("marketing / project fundamental") and 5 ("Legal(Legal requirement (ISO Standard)").)). FOF ¶¶ 90-91. Moreover, Dr. Slocum admitted he could not identify ***any*** prior art teaching the alleged paramount importance of lowered injection force. FOF ¶ 92. In fact, the prior art does not highlight injection force as a sole motivating factor, and instead discusses numerous other factors as important to injector pen design, including manufacturability, the ability to correct a dose, and minimizing the number of components. FOF ¶ 93.

Additionally, even if the POSA were guided primarily by injection force, the spreadsheet Dr. Slocum relies on to claim that using the threaded driver taught by Steenfeldt-Jensen would raise injection force has several flaws. FOF ¶ 94. For example, Dr. Slocum's spreadsheet only calculated allegedly additional forces but failed to account for forces that would be removed when using the threaded driver alternative, thus offsetting the calculated injection force. FOF ¶ 95. Because he had no professional experience with injector pens before this case, Dr. Slocum relied on Mr. Veasey's empirical claim that 0.1 was the appropriate coefficient of friction to use despite Dr. Slocum teaching his students at MIT that the coefficient of friction for commonly-used plastics in mechanical devices can range from 0.05 to 0.1. FOF ¶ 96. Dr. Slocum agreed in both instances that accounting for these differences would reduce the "51%" ratio, undermining his claim that the POSA would not implement the alternative embodiment described in Steenfeldt-Jensen. FOF ¶ 97. The values used in Dr. Slocum's spreadsheet underscore Dr. Slocum's unyielding acceptance of Mr. Veasey's empirical claims and fail to account for the

POSA's ordinary skill (and creativity). FOF ¶ 98. The POSA implementing Steenfeldt-Jensen's alternative could have easily reduced injection force, if that was even a concern necessary to address.[11] FOF ¶ 98; COL ¶¶ 20, 29-30.

b. Claim 22: Steenfeldt-Jensen And Chanoch Render Obvious A Piston Rod That Has "A Circular Cross-Section"

Steenfeldt-Jensen and Chanoch render claim 22 obvious because they disclose piston rods with circular cross-sections. FOF ¶ 100. Although Steenfeldt-Jensen describes the piston rod as "non-circular," that addresses only a portion of the piston rod, ignoring the ends, which Mr. Leinsing explained have a circular cross-section. FOF ¶ 101. Dr. Slocum's opinion that Steenfeldt-Jensen and Chanoch allegedly lack a piston rod with a circular cross-section appears to rest on the theory that the piston rod must be circular along the entire length of the piston rod. FOF ¶ 102. However, this improperly reads limitations into the claim. Claim 22 only requires "a" (i.e., at least one) circular cross-section. FOF ¶ 103; COL ¶¶ 1, 3, 6, 20. There is no requirement in claim 22 for what fraction of the piston rod must be circular or where the circular cross-section must be (ends, middle, etc.). FOF ¶ 104. As Dr. Slocum admitted on cross examination, a piston rod can have more than one "cross section."[12] FOF ¶ 105.

Rather than adding a brand-new limitation without support in the specification, as Dr. Slocum does to try to distinguish the prior art, the POSA would interpret claim 22 in view of the '844 patent specification. FOF ¶ 108; COL ¶¶ 2-3, 20. The '844 patent discloses a piston rod with two sets of threads, each of which result in a cross-section that is not perfectly circular.

[11] Notably, even if injection force did increase by about 51%, the allegedly higher injection force would still be acceptable to patients, which is yet another reason the POSA would not be dissuaded from the obvious alternative configuration described in Steenfeldt-Jensen and Chanoch. *See* FOF ¶ 99.

[12] Dr. Slocum also admitted that ends of a piston rod may be "journals" or "bearing[s]" that are round. FOF ¶ 106.

FOF ¶ 109. One of the sets of threads is described as "part" threads, meaning they do not encompass the full 360-degree circumference of the piston rod, again resulting in a cross-section that is not perfectly circular in the lone and preferred embodiment of the '844 patent. FOF ¶ 110; COL ¶ 2. The Great Britain application to which the '844 patent claims priority has clearer figures than the '844 patent and shows areas between the threads on the piston rod that have flats, which create a non-circular cross-section. FOF ¶¶ 111-12. The '844 patent also describes the piston rod as of "***generally*** circular section," and depicts the piston rod as having multiple types of cross sections. *See* FOF ¶¶ 108-12. Mr. Veasey further conceded that the SoloSTAR pen—which he testified corresponded to both development Concept 12 described in the GB application and the '844 patent—has an "***essentially*** round" piston rod. FOF ¶ 114. In view of the above facts and evidence, the POSA would not interpret claim 22 as requiring a "perfectly" circular cross-section "along its length"; rather, the POSA would understand claim 22 as requiring "a" (at least one) cross-section that is generally circular. FOF ¶ 113. Steenfeldt-Jensen and Chanoch disclose piston rods meeting those criteria.[13] FOF ¶¶ 116, 118.

By contrast, Dr. Slocum's argument that claim 22 refers somehow to only the "root diameter" of the piston rod, and therefore to only the portion "that does the work of providing the axial force," finds no basis in the '844 patent. FOF ¶ 115. Dr. Slocum's argument should be rejected for improperly attempting to create a new limitation without any basis in the '844 patent claims or specification.[14] COL ¶¶ 2-3, 20.

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[13] Sanofi is being inconsistent. Sanofi argues that the prior art lacks a piston rod with a circular cross-section because geometry that prevents rotation (*e.g.*, flats, slots, splines) makes the cross-section non-circular. But Sanofi also accuses the plunger rod of the Proposed Pen of infringement even though it has a so-called "key" (i.e., ***not*** a circular cross-section) that prevents rotation during dose administration. FOF ¶ 117.

[14] Dr. Slocum's argument should also be viewed skeptically, as it takes an approach inconsistent with Dr. Reinholtz's. Dr. Slocum tried to distinguish between cross-sections of the piston rod

(continued...)

c. Claim 30: A "Nut That Tracks Each Set Dose of Medicament" Is Obvious Over Steenfeldt-Jensen And The Prior Art

It was common in the art as of 2003 to use a nut member engaged with threads to track medication dosing, as Mr. Leinsing explained in his unrebutted testimony. FOF ¶ 119. The ISO standards, which DCA documents describe as "legal" requirements and ranked as the highest level of importance, would cause the POSA to add a nut because the standards require dose tracking so the pen "does not allow a larger dose to be preset than is left in the cartridge." FOF ¶ 120. Sanofi did not dispute that the POSA would be motivated to add, and could and would add, a dose tracking nut. FOF ¶ 121. Moreover, FlexPen—which, as described below, was known and used by others prior to the '844 patent's filing date—and Klitgaard demonstrate that it was well known in the prior art to use a nut to track each set dose of medicament. FOF ¶ 122.

3. FlexPen Renders The Asserted Claims Obvious

FlexPen qualifies as prior art to the '844 patent because it was "known or used by others" in the United States before March 3, 2003 (35 U.S.C. § 102(a)) and "in public use or on sale" in the United States before March 2, 2003 (35 U.S.C. § 102(b)). FOF ¶ 123; COL ¶ 25. The evidence establishes FlexPen was on sale and sold (and therefore in use) before March 2 or 3, 2003.[15] *See* FOF ¶¶124-27. For example, Novo Nordisk documents state that FlexPen was introduced in the U.S. in 2002 and IMS data shows U.S. sales between March 2002 and March

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based on whether they were "journal" bearings or threaded, based on their function. FOF ¶ 107. Dr. Reinholtz, however, ignored the fact that the teeth accused of providing audible clicks during dose cancelling for claim 25—allegedly part of the claimed "clutch"—are uninvolved with the clutching function. FOF ¶ 107. Whereas Dr. Reinholtz analyzes a component as a whole, Dr. Slocum's arguments for validity require parsing out portions of a component by function. Sanofi cannot have it both ways. *See* COL ¶¶ 1, 3.

[15] If FlexPen does not qualify as within "the scope and content of the prior art" as Sanofi contends, then the mathematical basis for Dr. Slocum's testimony that the modification to Steenfeldt-Jensen's fifth embodiment would result in a 51% increase in injection force is irrelevant for the purposes of obviousness because it is based on the dimensions of the FlexPen product and thus finds no basis in the prior art. FOF ¶ 125. Sanofi cannot have it both ways.

2003. FOF ¶ 124. Mr. Veasey, moreover, testified that DCA documents showing the FlexPen accurately represent the prior art device available before March 2003 because DCA engineers had used a FlexPen sample to create CAD drawings and perform other analyses. FOF ¶ 127.

Sanofi stipulated that the FlexPen discloses the same elements of the Asserted Claims as Steenfeldt-Jensen, which means most limitations in claim 21 and all limitations in claims 23-25. Sanofi further stipulated that FlexPen discloses all limitations of claim 30. FOF ¶ 128. Sanofi thus contested only whether FlexPen disclosed the limitations associated with threading on the driving member in claim 21. On direct examination, Dr. Slocum agreed that, for the purposes of obviousness, there is no difference between Steenfeldt-Jensen's fifth embodiment and the FlexPen. FOF ¶ 129. As discussed in Section IV.B.2. above, Steenfeldt-Jensen and Chanoch render the asserted claims obvious, and the POSA would implement the alternative described in Steenfeldt-Jensen in FlexPen (and Dr. Slocum failed to state any reasons to the contrary). FOF ¶ 130; *see generally* FOF ¶¶ 62-99. As a result, FlexPen, like Steenfeldt-Jensen, also renders obvious all asserted claims. FOF ¶ 131; COL ¶¶ 32-33, 36.

4. Giambattista Renders The Asserted Claims Obvious

a. Claim 21: Giambattista's Retract Nut Is Rotatably Fixed To The Housing

Sanofi agreed that Giambattista describes a pen injector that meets every one of the limitations recited in claim 21 except "a piston rod holder that is rotatably fixed relative to the housing." FOF ¶ 132. The "piston rod holder" in Giambattista is "retract nut 4," which has splines to prevent rotation of the lead screw when the device is used. FOF ¶ 133. Giambattista thus expressly discloses a piston rod holder that is rotatably fixed to the housing. FOF ¶ 133.

Sanofi nevertheless contended the only reason the retract nut does not satisfy claim 21 is because, in the infrequent circumstance where the user replaces an empty cartridge with a new, full, cartridge, the retract nut rotates to allow the user to push the piston rod back into the

housing and reset its position. *See* FOF ¶¶ 132, 134, 136. But there is no basis in the '844 patent to distinguish the piston rod holder disclosed in Giambattista. A plain reading of the claims and the '844 patent does not preclude a reusable device like the one described in Giambattista. FOF ¶ 135. Moreover, the only phases of operation described in the '844 patent are dose setting (including dose correction) and dose dispensing. *See, e.g.*, FOF ¶ 136. The retract nut in Giambattista is always rotatably fixed to the housing during both of those phases of operation. FOF ¶ 136. And even if the claim precluded a reusable device that allows a user to replace a spent cartridge, it would have been obvious to permanently affix the "piston rod holder" in Giambattista's device if the POSA were inclined to design a single-use (disposable) device instead. FOF ¶ 137; COL ¶¶ 29-31.

b. Claim 22: Giambattista Discloses A Piston Rod With A Circular Cross-Section

Giambattista renders claim 22 obvious because it discloses a leadscrew (i.e., piston rod) with circular cross-sections. FOF ¶ 138; COL ¶¶ 29-33; 36. Like Steenfeldt-Jensen and Chanoch, while Giambattista describes a piston rod having flats along a portion of its length, other portions of the piston rod, like its ends, have circular cross-sections and even the threaded portion is generally circular. FOF ¶ 139. As explained above, consistent with the '844 patent's specification, claim 22 only requires "a" (at least one) circular cross-section (*see* FOF ¶¶ 108-13), and there is no dispute that a piston rod can have more than one "cross section." *See supra*, section IV.B.2.b; FOF ¶ 139.

C. Secondary Considerations Do Not Rescue The '844 Patent

Defendants established a strong *prima facie* case of obviousness. Sanofi failed to rebut Defendants' evidence with objective indicia or alleged secondary considerations of nonobviousness. COL ¶ 42. Sanofi asserted that 1) a long-felt but unresolved need; 2) commercial success; and 3) industry praise allegedly support inferring nonobviousness of claims

21, 25, and 30.[16] FOF ¶¶ 140-143; COL ¶ 37. Sanofi's purported evidence does not support nonobviousness, however, because the proffered considerations suffer from hindsight and lack any nexus to any novel patented features of the asserted claims. FOF ¶¶ 140-174; COL ¶¶ 20, 38-39.

1. There Is No Nexus To The Alleged Commercial Success

Sanofi contended its Lantus SoloSTAR pen was commercially successful due to features claimed in the '844 patent. However, like other objective indicia of nonobviousness, "if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant." COL ¶¶ 38-41. Here, Sanofi failed to establish any nexus between the claims of the '844 patent and sales of Lantus SoloSTAR.

First, Sanofi failed to establish a nexus between SoloSTAR sales and the Asserted Claims. As an initial matter, Sanofi's own witness, named inventor Mr. Veasey, admitted the claims of the '844 patent do not require or guarantee any particular injection force, and the claims never even mention ease of use. FOF ¶ 146. Generic claims that a product is good and is patented are not legally sufficient. COL ¶¶ 20, 40, 47.

Second, Sanofi failed to explain why the alleged commercial success should not be attributed to marketing, unclaimed design features, and, even more apropos, the drug formulation (which is not claimed in the '844 patent) within the pen. FOF ¶¶ 144-149; *see* COL ¶¶ 46-49.

For example, Sanofi adopted a marketing "conversion strategy" in which Sanofi sought to move Lantus patients from vials to the SoloSTAR pen. FOF ¶¶ 159, 168; *see also* FOF ¶¶ 144-162. As Defendants' expert, Dr. McDuff, explained, this strategy accounts for much of

[16] Notably, Sanofi presented this alleged evidence as to claims 21, 25, and 30 only; Sanofi did not present any evidence of secondary considerations with respect to claim 22 of the '844 patent because Sanofi's commercial embodiment, the Lantus SoloSTAR, does not practice that claim. FOF ¶ 142.

Sanofi's SoloSTAR sales, and Sanofi failed to explain why any sales should be attributed to the pen itself as opposed to the drug inside of the pen (insulin glargine). Indeed, Sanofi's own contemporaneous documents show the focus for driving sales was the insulin glargine formulation inside the SoloSTAR, not the pen itself. FOF ¶¶ 148, 152, 159.

Further, prescription data for Lantus over 2002-2019 shows the prescription growth rate ***decreased*** after Sanofi introduced the Lantus SoloSTAR. FOF ¶ 148. If SoloSTAR truly drove sales, the prescription growth rate should have increased. FOF ¶ 148. Instead, the evidence shows that Sanofi's dominant position in the insulin glargine market—due to patents on insulin glargine and its formulation—drove sales. FOF ¶¶ 144-162; *see* COL ¶ 49.

2. The '844 Patent Did Not Fulfill A "Long-Felt But Unmet Need"

There was no long-felt but unmet need for the Lantus SoloSTAR pen. Sanofi tried to show, through Dr. Goland's testimony, that prior to March 2003 there was a long-felt but unmet need for an easy-to-use insulin pen with a low injection force. FOF ¶ 165. But the '844 patent does not claim any injection force or superior ease of use. Dr. Goland's assertions of a long-felt need boil down to her own current and personal praise of the Lantus SoloSTAR, which mimics the heavily promoted "core features" of the Lantus SoloSTAR described in Sanofi's training and marketing materials. FOF ¶¶ 164-168. Indeed, Dr. Goland was unable to identify any objective facts establishing there was any specific need in the industry, for how long this need may have been felt, or how the features in the Asserted Claims allegedly met those needs. FOF ¶¶ 165-171; *see* COL ¶ 43. In fact, Sanofi documents contradict Dr. Goland's assertion of any need for a pen with lower injection force, describing, for example, that doctors frequently challenged Sanofi's marketing regarding injection force, asking, "Why is injection force important[?]" and stating, "My patients don't have trouble with injections." FOF ¶¶ 168-169; COL ¶ 49.

As Dr. Biggs explained, because the SoloSTAR is substantially similar to other injector

pens, patients with difficulties operating one injection pen due to infirmities will likely face the same difficulties with the SoloSTAR; thus, the SoloSTAR did not meet any long-felt need with respect to improving access to pen-based self-injection of insulin. FOF ¶¶ 170. Any patented differences between the SoloSTAR and prior art injector pens—to the extent there even are any—are so inconsequential that they cannot be said to have resolved any long-felt but unmet need. *See* COL ¶ 45. Indeed, Sanofi has not even attempted to connect the alleged points of novelty—a rotatably fixed piston rod holder or threaded driving member (both of which are obvious for the reasons stated above)—with satisfaction of any alleged need for a pen that was easier to use. FOF ¶¶ 166-167; *see* COL ¶¶ 20, 38-41, 44.

3. Sanofi's Self-Funded Industry Praise Does Not Support Nonobviousness

Sanofi also claims industry awards show nonobviousness, but its purported evidence of industry praise falls well short of convincing. The two awards documents cited by Sanofi were promotional and self-imbued, failing to demonstrate any actual indicia relevant to obviousness. FOF ¶¶ 172-174; *see* COL ¶¶ 50-51. For example, Mr. Veasey admitted Sanofi applied for one of the awards upon a payment that could have been 1000 pounds. FOF ¶ 174. Further, the awards documents relied on by Sanofi focus on the Lantus SoloSTAR pen generally, there is no evidence the awarding entities ever considered the Asserted Claims of the '844 patent, and the awards are certainly not specific to any of the '844 patent's claimed features. FOF ¶¶ 172-174; COL ¶¶ 20, 50-51.

V. CONCLUSION

For the foregoing reasons, the Court should find the '844 patent not infringed and invalid and enter judgment in favor of Defendants. COL ¶¶ 62-64.

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